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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/350,518

07/09/1999

JOHN C. REED

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EXAMINER

SANG, HONG

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/350,518	Applicant(s) REED, JOHN C.	
	Examiner HONG SANG	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11,12,16,22-27,32-34,44,50-54,56,58-69,73-81 and 83-109 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,12,16,22-27,32-34,44,50-54,56,58-69,73-81 and 83-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Reed

1. Applicant's response filed on 7/23/2008 is acknowledged. Claims 11, 12, 16, 22-27, 32-34, 44, 50-54, 56, 58-69, 73-81, and 83-109 are pending. New claims 100-109 have been added. Claims 1-10, 13-15, 17-21, 28-31, 35-43, 45-49, 55, 57, 70-72 and 82 have been cancelled. Claims 67, 76, 78, 81 and 83 have been amended
2. Claims 11, 12, 16, 22-27, 32-34, 44, 50-54, 56, 58-69, 73-81, and 83-109 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 102

3. The rejection of claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 101, 103, 105, 107 and 109 under 35 U.S.C. 102(b) as being anticipated by Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) is maintained.

The response states that DCIS is different from stage I breast cancer and stage II breast cancer, as evidenced by Exhibit 1 and Exhibit 2 which describes DCIS as a non-invasive type of breast cancer, and stage 0 of breast cancer. Unlike in DCIS, breast cancer at stage I or stage II is considered to be invasive. Stage I has no lymph node involvement, whereas stage II can have a tumor of a given size without lymph node involvement or can have lymph node involvement. Stage III and stage IV are also invasive breast cancers, staged based on tumor size, lymph node involvement and

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metastasis (see Exhibit 2). Additional details and characteristics of the stages of breast cancer are provided in Exhibit 3. Turner et al. provides no teaching of the stage of the breast cancer samples. Turner et al. is silent as to whether the breast samples were stage I, II, III or IV or any of the thirteen TNM stage groupings.

Applicants' arguments have been carefully considered but are not found persuasive. Turner et al. determined the expression of BAG-1 in benign breast epithelium (BBE), ductal carcinoma in situ (DCIS), and invasive carcinoma (IC) of the breast in 87 breast cancer patients (see abstract lines 3-5), of which 82 patients have IC and 5 patients have pure DCIS (see abstract lines 6-7). Turner et al. teach the slides were rated on a scale of intensity and % distribution within the BBE, DCIS and IC components (see lines 8-9). Turner et al. teach that the patients had a median follow-up of 13 years. Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. While the Exhibits 1-3 define the DCIS is stage 0 breast cancer, the instant specification specifically teaches that stage I of breast cancer requires no lymph node involvement, and stage II of breast cancer involves either no lymph node involvement and a large primary tumor or initial lymph node involvement and a small primary tumor (see specification, page 25, lines 17-22). The specification further teaches that "prior to lymph node involvement" refers to the detectable presence of cancer cells in the organ of the primary tumor, but the lack of a detectable presence of cancer cells in any lymph nodes (see page 25, lines 32-34). According to the definition of the stage I and stage II of breast cancer provided by the instant specification, the

DCIS reads on the stage I breast cancer and stage II with no lymph node involvement.

As such, Turner et al. teach all limitations of the claims.

Claim Rejections - 35 USC § 103

4. The rejection of claims 11, 12, 16, 22, 24-27, 32-34, 44, 50-53, 56, 58-61, 67-69, 73, 75-81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 100-109 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sano et al. (US patent NO. 5665539) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Sano et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sano et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 101, 103, 105, 107 and 109 has been set forth above (see paragraph 3). Moreover, Turner et al. teach determination of the expression of BAG-1 in DCIS as well as invasive carcinoma (IC) of the breast in breast cancer patients (see abstract). Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. As such, Turner et al. teach detection of BAG1 in both non-invasive and invasive breast

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carcinoma, and further correlation of the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1. While Turner et al. do not explicitly disclose the stage of the invasive breast carcinoma used in their study, detecting BAG-1 in non-invasive and invasive breast carcinoma of stages I-IV using the method of Turner et al. would have been obvious to one skilled in the art in view of the teachings of Turner et al. Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Sano et al.

5. The rejection of claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-68, 73, 75-79, 81, 83-99 and new claims 100-109 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Sauter et al. (British Journal of Cancer, 1997, 76(4): 494-501) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Sauter et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Sauter et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 101, 103, 105, 107 and 109 has been set forth above (see paragraph 3). Moreover, Turner et al. teach determination of the expression of BAG-1 in DCIS as

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well as invasive carcinoma (IC) of the breast in breast cancer patients (see abstract).

Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC.

As such, Turner et al. teach detection of BAG1 in both non-invasive and invasive breast carcinoma, and further correlation of the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1. While Turner et al. do not explicitly disclose the stage of the invasive breast carcinoma used in their study, detecting BAG-1 in non-invasive and invasive breast carcinoma of stages I-IV using the method of Turner et al. would have been obvious to one skilled in the art in view of the teachings of Turner et al. Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Sauter.

6. The rejection of claims 11, 16, 22-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 100-109 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Takayama et al. (Cancer Res. 1998, 58: 3116-3131, IDS) is maintained.

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Takayama et al. does not cure the deficiencies of Turner et a., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Takayama et al.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 101, 103, 105, 107 and 109 has been set forth above (see paragraph 3). Moreover, Turner et al. teach determination of the expression of BAG-1 in DCIS as well as invasive carcinoma (IC) of the breast in breast cancer patients (see abstract). Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. As such, Turner et al. teach detection of BAG1 in both non-invasive and invasive breast carcinoma, and further correlation of the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1. While Turner et al. do not explicitly disclose the stage of the invasive breast carcinoma used in their study, detecting BAG-1 in non-invasive and invasive breast carcinoma of stages I-IV using the method of Turner et al. would have been obvious to one skilled in the art in view of the teachings of Turner et al. Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Takayama.

7. Claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-68, 73, 75-79, 81, 83-99, and new claims 100-109 under 35 U.S.C. 103(a) as being unpatentable over Turner et al. (Breast Cancer Research and Treatment (Oct. 1997), 46(1): p69, print) in view of Love (US Patent No. 6,221,622B1, Date of Patent 4/24/2001, earliest effective filing date 4/28/1998).

The response states that Turner et al. does not teach stage I and state II with no lymph node involvement for the same reasons given above, and Love does not cure the deficiencies of Turner et al., therefore, the claimed methods are unobvious over Turner et al. alone or in combination with Love.

Applicants' arguments have been carefully considered but are not found persuasive. The reason that Turner's reference anticipates claims 11, 16, 22, 24-27, 32, 34, 44, 50-54, 56, 58-61, 67, 68, 73, 75-79, 81, 83-86, 88, 89, 91, 92, 94, 95, 97, 98, and new claims 101, 103, 105, 107 and 109 has been set forth above (see paragraph 3). Moreover, Turner et al. teach determination of the expression of BAG-1 in DCIS as well as invasive carcinoma (IC) of the breast in breast cancer patients (see abstract). Turner et al. correlated the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1 in the cytoplasm and nucleus of BBE, DCIS, and IC. As such, Turner et al. teach detection of BAG1 in both non-invasive and invasive breast carcinoma, and further correlation of the 10-year overall survival and distant disease free survival to the overexpression level of BAG-1. While Turner et al. do not explicitly disclose the stage of the invasive breast carcinoma used in their study, detecting BAG-1 in non-invasive and invasive breast carcinoma of stages I-IV using the method of Turner et al. would have been obvious to one skilled in the art in view of the teachings of Turner et al. Therefore, the claimed methods are deemed obvious in view of the teachings of Turner and Love.

Conclusion

8. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
10/3/08

/Christopher H Yaen/
Primary Examiner, Art Unit 1643